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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,971	04/25/2006	Sanjay Suri	06-40079-US	8129

7590 02/24/2009
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EXAMINER

MABRY, JOHN

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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02/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,971	Applicant(s) SURI ET AL.	
	Examiner JOHN MABRY	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/27/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objection(s)

Claim 47 is objected to because of the following informalities: The term "diol" is not defined by the claim. Does Applicant intend to claim any and all possible diol compounds? Examiner can only assume that Applicant is referring to compound VII. Examiner respectfully requests that Applicant label this term appropriately with proper roman numeral.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47, 48, 53 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "C \equiv 8" in claim 53 is indefinite. The term "C \equiv 8" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Does Applicant intend for this term to mean an alkyl chain that consists of approximately and/or exactly eight carbons? If so, this does not coincide with the examples provided in dependent claim 53. Claim 53 lists organic acids with less than 4 alkyl chain carbons.

Regarding claims 47, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

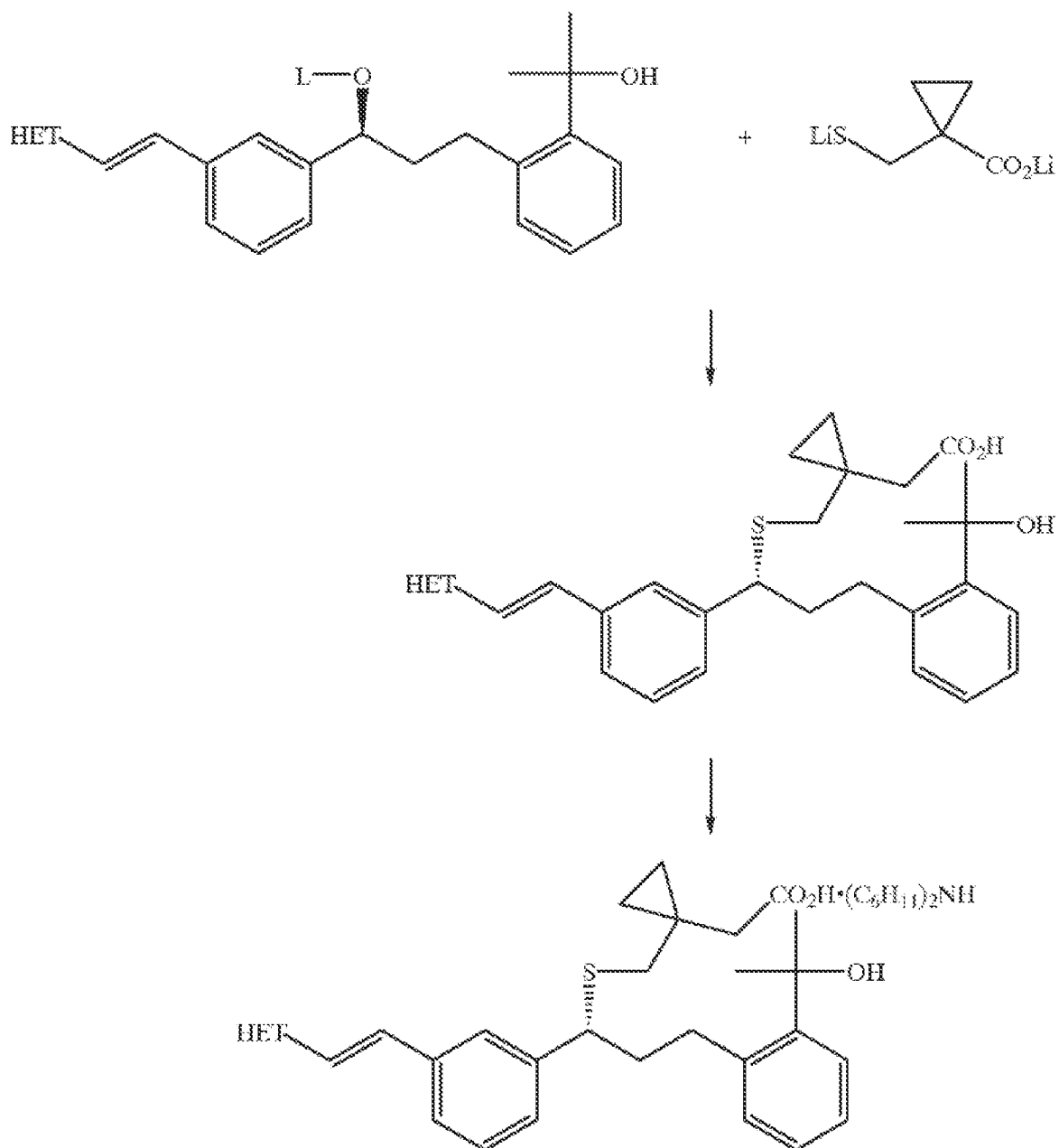
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 44-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhupathy et al (US 6,320,052) – see entire reference, Scheme 3 and sections as indicated below.

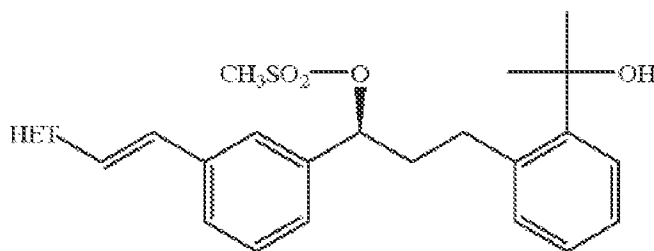
US '520 discloses a method for the preparation of montelukast acid in pure form and a sodium salt, which involves the step of coupling the dilithium salt of 1-(mercaptomethyl)cyclopropaneacetic acid (IX) with sulfonate of formula II. The 1-(mercaptomethyl)cyclopropaneacetic acid (IX) is first converted into the dilithium dianion by contacting IX with a lithium base such as n-butyl lithium in hexanes (or any alkane solvent). The reaction is carried out in an inert organic solvent such as THF, toluene or a mixture and at a temperature of below 0° C, typically at about -5° C or lower (see columns 7, lines 38-40).

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SCHEME 3

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The sulfonate (VIII) is prepared by reacting diol (VII) with methane sulfonyl chloride in toluene, acetonitrile and in the presence of diisopropyl ethyl amine at -25o C (see column 6, lines 64-67) Example 6, column 15).



The sulfonate (VIII) is then added to the solution of the dilithium dianion is then added to the solution of the dilithium dianion in a solution of organic solvent such as THF. The reaction mixture is maintained at below about 0° C, generally at about -5° C until the completion within about 10 h. The reaction solution containing the desired product is then treated with a water soluble carboxylic acid such as acetic acid, oxalic acid and the like to provide the free acid form of a compound of VI (see columns 7, lines 57-64).

The dicyclohexylamine (DCHA) salt is prepared by taking the dicyclohexylamine and adding to a solution of VI in ethylacetate, followed by hexanes then the dicyclohexylamine salts crystallizes. A second crystalline form of the DCHA salt of formula X is obtained by crystallization from toluene/heptane. The combined crystals are diluted with additional toluene and heptane is added to the toluene solution (see columns 8, lines 45-54).

The DCHA salt of formula X is added to mixture of an organic solvent and water, where organic solvent is an aromatic hydrocarbon, preferably toluene; an ester such as

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ethyl acetate; and ether such as THF or a mixture thereof, for example toluence/THF.

To this suspension at room temperature (RT), is added a water soluble organic acid, for example acetic acid, oxalic acid, tartaric acid and the like. The organic layer containing the free acid is then treated with a source of sodium ion, for example sodium hydroxide (see column 9, lines 15-31). The desired product, montelukast sodium (I), was recovered in greater than 99+% yield (see column 21, lines 23-31).

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's primary examiner can be reached at (571) 272-0684, first, or the Examiner's supervisor, Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/John Mabry/
Examiner
Art Unit 1625

/Rita J. Desai/
Primary Examiner, Art Unit 1625